

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-27 (Previously Cancelled)

Claim 28 (Currently Amended): A method of modulating an immune response to bee venom, said method comprising administering a substantially pure bee venom polypeptide consisting ~~essentially~~ of the amino acid sequence of SEQ ID NO:1 to a subject in need thereof in an amount sufficient to ~~stimulate T cell proliferation~~ inhibit an immune response by the subject against said bee venom.

Claim 29 (Currently Amended): The method of claim 28, further comprising administering a second bee venom polypeptide to said subject, wherein the second bee venom polypeptide is selected from the group consisting of phospholipase A₂, hyaluronidase, allergen C, mellitin, adolapin, minimine, and acid phosphatase.

Claim 30 (Cancelled)

Claims 31-35 (Previously Cancelled)

Claim 36 (Currently Amended): The method of claim 28, further comprising administering one or more additional bee venom polypeptides to said subject, wherein one or more additional bee venom polypeptides is selected from the group consisting of phospholipase A₂, hyaluronidase, allergen C, mellitin, adolapin, minimine, and acid phosphatase.

Claims 37-43 (Previously Cancelled)

Claims 44-49 (Cancelled)

REMARKS

Claims 28, 29 and 36 are pending in the instant application. Applicant has cancelled claims 30 and 44-49, without prejudice or disclaimer, and has amended claims 28, 29 and 36. The amendments made herewith are fully supported by the as-filed specification. Thus, no new matter has been added.

Applicant has amended claim 28 to recite a method of modulating an immune response to bee venom by “administering a substantially pure bee venom polypeptide consisting of the amino acid sequence of SEQ ID NO: 1.” Applicant has also deleted the phrase “stimulate T-cell proliferation” and replaced it with the phrase “inhibit an immune response.” Support for these amendments can be found, for example, at least at page 3, lines 12-14; page 8, lines 3-4.

Applicant has also amended claim 29 to recite specific second bee venom polypeptides, and has amended claim 36 to recite specific one or more additional bee venom polypeptides. Support for these claim amendments can be found, for example, at least at page 3, lines 8-10 and lines 15-18.

CLAIM REJECTIONS - § 112, FIRST PARAGRAPH

Enablement

The Examiner has rejected claims 28-30, 36 and 44-49 under 35 U.S.C. § 112, first paragraph, contending that the specification is not enabling for a method of modulating an immune response to bee venom “(1) comprising administering a substantially pure bee venom polypeptide ‘**consisting essentially of**’ the amino acid sequence of SEQ ID NO:1 to a subject in need thereof in an amount sufficient to stimulate T-cell proliferation by the subject against said bee venom, (2) ...comprising administering a substantially pure bee venom polypeptide ‘**consisting essentially of**’ the amino acid sequence of SEQ ID NO:1 to a subject in need thereof in an amount sufficient to stimulate T-cell proliferation by the subject against said bee venom further comprising administering any ‘second bee venom polypeptide’ ...or analogs or derivatives thereof, (3) the said method further comprising administering one or more additional

bee venom polypeptides to said subject, (4) ...comprising administering a composition comprising two overlapping bee venom polypeptide fragments, wherein said overlapping fragments form the entire amino acid sequence of SEQ ID NO:1 to a subject in need thereof, in an amount sufficient to stimulate T-cell proliferation by the subject against said bee venom, wherein said overlapping fragments such as between '32 and 45 amino acids in length', (5) the said method further comprising administering one or more additional 'bee venom polypeptides' to said subject, (6) the said method wherein said two overlapping bee venom polypeptide fragments overlap by 3, 5, or 10 amino acids, and wherein said polypeptide fragments are between 32 and 40, or between 32 and 40 and between 32 and 45 amino acids in length, respectively for modulating any immune response." (Office Action at page 2-3). In order to facilitate the prosecution of this case, Applicant has herewith cancelled claims 30 and 44-49, without prejudice or disclaimer. Thus, this rejection, as it refers to these claims, is moot and should be withdrawn. Applicant respectfully traverses this rejection as it applies to pending claims 28, 29 and 36.

The Examiner has acknowledged that the specification is enabling for a method of modulating an immune response by administering a substantially pure polypeptide consisting of the amino acid sequence of SEQ ID NO: 1 in an amount sufficient to inhibit an immune response by the subject against said polypeptide, said method further comprising a second bee venom polypeptide selected from the group of polypeptides recited in claim 30. (Office Action at page 2).

Applicant has herewith amended independent claim 28 to replace the term "consisting essentially of" with the term "consisting of." Moreover, Applicant has also replaced the phrase "stimulate T-cell proliferation" with the phrase "inhibit an immune response." Thus, claim 28 as amended recites a substantially pure bee venom polypeptide consisting of the amino acid sequence of SEQ ID NO:1 as well as a specific way of modulating an immune response (*i.e.*, inhibiting an immune response). Applicant has amended claims 29 and 36 to recite the administration of a second bee venom polypeptide or one or more additional bee venom polypeptides, respectively, wherein the additional polypeptide(s) are selected from the group consisting of phospholipase A₂, hyaluronidase, allergen C, mellitin, adolapin, minimine, and acid phosphatase. As acknowledged by the Examiner, the specification is enabling for such claims

(See, Office Action at page 2). Thus, this rejection, as it applies to amended claims 28, 29 and 36, is overcome and should be withdrawn.

Written Description

The Examiner has also rejected claims 28-30, 36 and 44-49 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention. Applicant has cancelled claims 30 and 44-49, without prejudice or disclaimer. Thus, this rejection, as it refers to these claims, is moot and should be withdrawn. Applicant respectfully traverses this rejection as it applies to pending claims 28, 29 and 36.

As noted, claim 28 (and dependent claims 29 and 36) has been amended to recite a substantially pure bee venom polypeptide consisting of the amino acid sequence of SEQ ID NO:1 as well as a specific way of modulating an immune response. Applicant has also amended claims 29 and 36 to recite a second bee venom polypeptide or one or more additional bee venom polypeptides, respectively, that are selected from the group consisting of phospholipase A₂, hyaluronidase, allergen C, mellitin, adolapin, minimine, and acid phosphatase. Support for these amendments is found, for example, at least at page 3, lines 12-14 and page 8, lines 3-4. Thus, Applicant contends that independent claim 28 (and dependent claims 29 and 36), as amended herein, contains subject matter that is sufficiently described in the specification so as to reasonably convey to those skilled in the art that Applicant was in possession of the claimed invention. Accordingly, Applicant requests that the rejection of these claims be withdrawn.

New Matter

The Examiner has also rejected claims 28-30, 36 and 44-49 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention (See, Office Action at pages 11-12). As noted, Applicant has cancelled claims 30 and 44-49, without prejudice or disclaimer. Thus, this rejection as it refers to these claims, is moot and should be withdrawn. Applicant respectfully traverses this rejection as it applies to pending claims 28, 29 and 36.

Serial No. 09/506,978
Applicant: Spertini

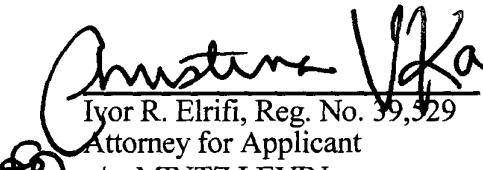
The Examiner states that the term “consisting essentially of” in independent claim 28 (and, thus, dependent claims 29 and 36) represents a departure from the originally filed specification and claims. Applicant has replaced the term “consisting essentially of” with the term “consisting of”. Thus, this rejection is moot and should be withdrawn.

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CONCLUSION

On the basis of the foregoing amendments and remarks, Applicant respectfully submits that the pending claims are in condition for allowance. Should any questions or issues arise concerning this application, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,


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